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| 09/832,273      | 04/10/2001  | Roland Cherif-Cheikh | 05339-014003        | 2832             |

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| EXAMINER |
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LAM, ANN Y

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9M.

## Office Action Summary

Application No.

09/832,273

Applicant(s)

CHERIF-CHEIKH, ROLAND

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 6-8 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Double Patenting***

Claims 6-8 and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,463 in view of Hutson, 5,242,416. Cherif-Cheikh '463 discloses the invention substantially as claimed (see claim 1.) Also, the '463 housing is capable of containing a liquid and dry drug composition wherein the liquid and dry drug composition are combined in the housing prior to injection.

However, '463 does not teach a removable cap which covers the sleeve. Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed.

Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath, and Hutson further teaches that providing a cap on a sheath protects the needle, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after use, as taught by Hutson.

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Claim 25 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,695,463 in view of Hutson, 5,242,416, and further in view of Whitley, 5,399,170.

Cherif-Cheikh '463 discloses the invention substantially as claimed, except for a removable cap which covers the sleeve, and except for a releasable lock to inhibit the movement of the plunger into the housing.

Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed. Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath and Hutson further teaches that providing a cap on a sheath protects the needle, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after use, as taught by Hutson.

Moreover, Whitley '170 also discloses a syringe with a protective sheath, and further discloses a releasable lock as claimed in order to prevent movement of the plunger prior to use, see column 3, lines 6-17. It would have been obvious to provide a releasable lock as taught by Whitley on the Cherif-Cheikh '463 syringe, as it would be desirable to prevent movement of the plunger prior to use.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al., 5,634,906, in view of Hutson, 5,242,416.

Haber et al. disclose the invention substantially as claimed. In particular, Haber et al. disclose an injection device comprising a hollow housing (6, 26 and 42) having a proximal and distal end, said distal end being capable of containing a liquid and a dry drug composition wherein the liquid and dry drug composition are combined in the housing prior to injection;

a hollow needle (36) affixed to the distal end of the housing and extending longitudinally within said housing;

a plunger (44, see column 5, lines 39-42) arranged to slide within the proximal end of the housing;

a hollow sleeve (24) slidably connected to the distal end of the housing and arranged to cover the needle prior to injection (see Figure 3) and to retract into the housing during injection (see Figure 4);

wherein the device is designed such that when the sleeve is pressed against the subject, and when the plunger is pushed into the housing, the composition is pushed from the housing through the needle and into the subject (see column 6, lines 6-11.)

As to claim 7, the proximal end of the housing (26) comprises a flange (see proximal end of 26.)

As to claim 8, the proximal end of the plunger (44) comprises a flange (see 44 in Figure 1).

As to claims 23 and 24, the housing (26) contains the liquid or semi-solid composition.

However, Haber et al. do not disclose a removable cap which covers the sleeve.

Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed. Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after use, as taught by Hutson.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al., 5,634,906, in view of Hutson, 5,242,416.

Haber et al. disclose the invention substantially as claimed, except for a removable cap which covers the sleeve, and except for a releasable lock to inhibit the movement of the plunger into the housing.

In particular, Haber et al. disclose an injection device comprising a hollow housing (6, 26 ad 42), a hollow needle (36) affixed to the distal end of the housing and extending longitudinally within said housing; a plunger (44, see column 5, lines 39-42) arranged to slide within the proximal end of the housing; a hollow sleeve (24) slidably connected to the distal end of the housing and arranged to cover the needle prior to injection (see Figure 3) and to retract into the housing during injection (see Figure 4); wherein the device is designed such that when the sleeve is pressed against the subject, and when the plunger is pushed into the housing, the composition is pushed from the housing through the needle and into the subject (see column 6, lines 6-11.)

However, Haber et al. do not disclose a removable cap which covers the sleeve.

Hutson discloses a syringe having a retractable sleeve (206) arranged to cover the needle. Hutson further discloses a cap (62 or 250) and teaches that the needle is protected by the cap (see column 8, lines 12-13) and that the cap may be placed on the sheath to protect the needle temporarily prior to additional use, where intermittent injections are required, for example, and the cap may be attached after use and the entire assembly may be disposed. Since both Cherif-Cheikh and Hutson teach a syringe with a protective sheath, it would have been obvious to one of ordinary skill in

the art at the time the invention was made to provide a removable cap as taught by Hutson on the Cherif-Cheikh sleeve in order to protect the needle before, during or after

Moreover, Whitley '170 discloses a syringe with a protective sheath and further discloses a releasable lock as claimed in order to prevent movement of the plunger prior to use, see column 3, lines 6-17. It would have been obvious to provide a releasable lock as taught by Whitley on the Cherif-Cheikh '463 syringe, as it would be desirable to prevent movement of the plunger prior to use.

### ***Response to Arguments***

With respect to Applicant's arguments regarding the rejection under Haber, Applicant's arguments are not persuasive based on the new rejection under Haber as described above.

Applicant argues on page 10 that the Haber device is not configured to contain a liquid or semi-solid composition. Examiner asserts that the Haber device is capable of containing a liquid or semi-solid composition and therefore meets the claimed limitation.

Applicant also argues on page 10 that the needle of Haber does not extend within the housing, but only through the medication cartridge housing. Under the new rejection above, the cartridge is considered part of the claimed housing. Elements (6, 26 and 42) are considered part of the housing.

Applicant also argues on page 10 that the housing of Haber retracts into the sleeve, rather than the sleeve retracting into the housing as claimed by Applicant.



Under the new rejection above, the housing in Haber includes elements (6, 26 and 42), and therefore the sleeve (24) retracts into the housing (6), see figure 4.

With respect to Applicant's arguments on page 11 regarding the rejection under Hutson, Applicant's arguments are not persuasive. Applicant argues that Hutson does not teach or suggest modifying the Haber device to reconfigure the housing so that it can accommodate a liquid or semi-solid composition. The housing (6, 26 and 42) is configured to contain a liquid and a dry drug composition wherein the liquid and dry drug composition are combined in the housing prior to injection, since it is capable of containing a liquid and a dry drug composition as claimed.

Applicant also argues on page 8 that the present application is patentably distinct from the device claimed in the Cherif-Cheikh '463 patent because the present invention does not contain a rod to push the medicament contained in the hollow needle out but does contain a removable cap to protect the needle and the sleeve prior to use. In response, Examiner reasserts that the relevant claims are rejected under obvious type double patenting and it would have been obvious to provide a cap as claimed in view of Hutson as described above.

Applicant also argues on page 9 that the '463 patent does not teach or suggest either that the rod used in the '463 patent can be eliminated or that the housing could be configured so as to be pre-filled with a liquid or medicament. Examiner reasserts that the '463 device is configured to contain a composition prior to injection as claimed because it is capable of containing a composition prior to injection.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 

  
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9/7/07